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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/603,320	06/26/00	BURZYNSKI S	BURG:046/KAM

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EXAMINER	
BAHAR, M	
ART UNIT	**PAPER NUMBER**
1617	6

DATE MAILED: 01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/603,320	BURZYNSKI, STANISLAW R.	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) 5-7,9-18 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4 and 8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Detailed Action

The applicant's response to the restriction requirement and amendments submitted November 27, 2000 is acknowledged.

Applicant's election with traverse of the invention of Group I in Paper No. 4 submitted November 27, 2000 is acknowledged. The traversal is on the ground(s) that the distinctness among the groups has not been clearly shown. In part A of his response, the applicant states that restriction is improper because the examiner has asserted that "Group I has a different mode of operation than Group II" with no data or reasoned argument to support this assertion. The examiner draws applicant's attention to page 3 of the restriction requirement where the examiner has presented a reasoned argument that the invention in Group I has a different mode of operation than that of Group II because Group I is drawn to a method of treating hypercholesterolemia or hypertriglyceridemia by administering a composition comprising one compound of formulae I, III or IV, whereas Group II is drawn to method of treating hypercholesterolemia or hypertriglyceridemia by administering a composition comprising two or more of the compounds of formulae I, III and IV.

Further in section A of his remarks, applicant states that in order for the inventions to be unrelated the examiner must show that the inventions operate by a different mode and that the inventions are "not disclosed as capable of use together." The examiner refers the applicant to section 806.04(A) of the MPEP where examples defining 806.04 are provided. Section 806.04 in relevant part states:

> "Two different combinations, not disclosed as capable of use together, having different modes of operation, different functions or different effects are independent..."

The applicant can clearly see that meeting any one of the criteria enumerated in part (A) satisfies the requirement for independent inventions. As applied *mutatis matandis*, reasoning used to demonstrate that Groups I and II are drawn to different inventions above, Groups III and IV are also patentably distinct from one another.

Applicant's argument that the restriction of Groups III and IV from Group I is improper is not found persuasive because lowering cholesterol can be achieved by using other hypolipidemic agents. The claimed method or process in Group I is that of inhibiting hypercholesterolemia (or hypertriglyceridemia). The product of Groups III and IV is the composition comprising compounds represented by formulae I, III and/or IV. The process as claimed for inhibiting hypercholesterolemia may be practiced with a range of materially different products, compounds (or compositions containing the same) which reduce cholesterol including those discussed in the restriction requirement of 10/24/00.

Applicant's remarks regarding the asserted common practice to examine method and composition/compound claims in the same application have been considered but are not persuasive. Please note regarding the cited patents that patents are property and are not available as precedent. Further, note that the restriction requirement between the product (composition) and methods of use herein is deemed proper as distinctness among these inventions has been shown under MPEP 806.05(h) in the restriction requirement herein.

Applicant's election without traverse of sodium salt of phenylacetylglutamine for Formula I, sodium salt of phenylacetylisoglutamine for Formula III and sodium salt of phenylacetic acid for Formula IV in Paper No. 4 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-7, 9-15 and 17-18 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in Paper No. 4.

Claim 16 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

Claims 1-4 and 8 are examined on the merits herein.

The claims have been examined in so far as they read on the elected invention and species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's admissions regarding the prior art at pages 2-3 of the specification in view of Hendry et al (USPN 5,238,947).

Applicant discloses that compounds such as 3-phenylacetylamino-2,6-piperidinedione and its hydrolysis products are known to block a reaction in the pathway of cholesterol biosynthesis, and as a result these compounds may lower serum cholesterol level. See page 3, lines 18-18 in the specification particularly.

Applicant's admissions regarding the prior art do not expressly disclose any relationship between the sodium salt of phenylacetylglutamine and 3-phenylacetylamino-2,6,piperidinedione. Moreover, applicant's admission do not expressly teach the therapeutic amounts employed herein, nor do they teach compositions containing the elected compound, phenylacetylglutamine sodium.

Hendry et al. discloses that the initial hydrolysis product of 3-phenylacetylamino-2,6-piperidinedione is phenylacetylglutamine, which is produced in vivo from phenylacetic acid and glutamine. In fact, Hendry et al. teaches that 3-phenylacetylamino-2,6-piperidinedione may be cyclized from phenylacetylglutamine in vivo. (Col. 2 lines 40-44).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ phenylacetylglutamine (or any salt thereof) in lieu of 3-phenylacetylamino-2,6-piperidinedione as cholesterol lowering agents in methods to inhibit or treat hypercholesterolemia.

One of ordinary skill in the art would have been motivated to combine these teachings in order to employ phenylacetylglutamine sodium in a method of treating or inhibiting hypercholesterolemia because phenylacetylamino-2,6-piperidinedione is known to be hydrolyzed in a host in vivo to produce phenylacetylglutamine. Therefore, similar antihypercholesterolemic effects in the host for both compounds would be reasonably expected. Given the current state of the art, determining the active ingredient dosage level is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said Skilled Artisan. The optimization of amounts of active ingredients to be employed is considered within the skill of the artisan.

Further, the incorporation of known active agents in compositions with pharmaceutical carrier materials is conventional in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
December 13, 2000

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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